Claims

add B

- 1. A package for a pharmaceutical product, particularly a liquid ophthalmic composition, such as an ophthalmic solution, gel or ointment, for example a tube or a dropper bottle assembly used to dispense said product, wherein said package is made of a specific form of polypropylene and wherein said package shows after an autoclaving processing of at least 121 °C and for at least 20 minutes no deformation such as shrinkage or blowing-up and retains a sufficient high squeezability in order to dispense said product.
- 2. A package according to claim 1, wherein said package meets the requirements of the European Pharmacopoeia, 3rd. edition (1997) and the EU-regulation.
- 3. Package of claim 1 or 2, wherein said package comprises a plastic bottle (2) for holding said product to be dispensed, a plastic nozzle tip (3) for dispensing said product and a cap (5) for closing said bottle.
- 4. A package according to claim 3, wherein said bottle (2) having a neck portion (4) that includes an externally threaded portion (15) and an outer rim which defines an outlet of the bottle, and said nozzle tip (3) being in fluid contact with said outlet of said bottle and having an dispensing passageway (7) for allowing liquid within said bottle (2) to pass out of an outlet (8) of said nozzle tip (3), and said cap (5) having internal threads for engagement with said externally threaded portion (15) of said neck portion (4).
- 5. A package according to claim 3 4, wherein said bottle (2) is made of a specific form of polypropylene, the nozzle tip (3) is made of a specific form of polypropylene and the cap (5) is made of a specific form of polypropylene and/or of high density polyethylene.
- 6. A package according to claim 3 5, wherein said bottle (2) is made of Appryl 3020 SM 3, the nozzle tip (3) is made of Appryl 3020 SM 3, and the cap (5) is made of HDPE GC 7260 or of polypropylene.
- 7. A package according to any of claims 3 to 6, wherein the bottom (12) of the bottle (2) has a concave configuration.

- 8. A package according to any of claims 1 to 7, wherein the wall thickness of the package, particularly the bottle (2) is in the range of 0.3 mm to 0.6 mm.
- 9. A package according to any of claims 1 to 8, wherein the wall thickness of the package, particularly the bottle (2) is 0.45 mm.
- 10. Method for sterilizing a pharmaceutical package comprising the steps, placing closed package into an autoclaving chamber, adjusting the temperature and the pressure in said chamber as a function of time in accordance to the prerequisites of the material of said package, wherein a counter pressure is generated in said chamber and wherein this is regulated electronically via computer control, and wherein said counter pressure avoids a deformation such as a blowing-up of said package.
- 11. Method of claim 10, wherein the pressure value is adjusted to the size of the packages to be sterilized.
- 12. Method of claim 10, wherein the pressure value is adjusted to the type of polypropylene.
- 13. Method of claim 10, wherein said package is a bottle, more preferably a PP-bottle.
- 14. Package of claim 5 9, wherein the physical chemical properties of said polypropylene meet the requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).